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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/763,949	01/23/2004	Andrei Darievich Mirzabekov	U 014998.5	5066
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LADAS & PARRY LLP 1040 Avenue of the Americas NEW YORK, NY 10018-3738			EXAMINER STEELE, AMBER D	
			ART UNIT 1639	PAPER NUMBER
			NOTIFICATION DATE 03/24/2011	DELIVERY MODE ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary

Application No.

10/763,949

Applicant(s)

MIRZABEKOV ET AL.

Examiner

Amber D. Steele

Art Unit

1639

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 March 2010.
2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 52-62 and 64-78 is/are pending in the application.
4a) Of the above claim(s) 66-67, 69-71, and 76-77 is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 52-62, 64, 65, 68, 72-75, and 78 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☒ The drawing(s) filed on 21 July 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on March 23, 2010 has been entered.

Status of the Claims

2. Claims 1-34 were originally filed on January 23, 2004.

The amendment to the claims received on October 3, 2006 canceled claims 1-17 and added new claims 35-51.

The amendment to the claims received on May 23, 2007 canceled claims 18-51 and added new claims 52-77.

The amendment to the claims received on October 1, 2007 changed the status identifiers only.

The amendment to the claims received on November 27, 2007 amended claims 52, 54, and 59.

The amendment to the claims received on December 9, 2008 amended claims 52, 61, and 63.

The amendment to the claims received on March 23, 2010 amended claim 52, canceled claim 63, and added new claim 78.

Claims 52-62 and 64-78 are currently pending.

Claims 52-62, 64, 65, 68, and 72-75 are currently under consideration.

Election/Restrictions

3. Regarding the initial restriction, applicants elected, without traverse, Group XIX (claims 52-75) in the reply filed on October 1, 2007. Claims 76-77 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected inventions. Regarding the secondary restriction, applicants elected, without traverse, Group I (claims 65 and 68; linking claims 52-64 and 72-75) in the reply filed on March 24, 2008. Claims 66-67 and 69-71 are

withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected inventions, there being no allowable generic or linking claim.

Priority

4. The presently claimed invention claims status as a CON of PCT/RU01/00445 filed October 26, 2001 and claims foreign priority to RU 2001120905 filed July 25, 2001.

New Objections

Claim Objections

5. Claim 52 is objected to because of the following informalities: a space should be present between “diacrylate” and “and” (see second to last line). In addition, the specific species of B should be recited in line 5 (i.e. B is...). Appropriate correction is required.

6. Claim 78 is objected to because of the following informalities: a period is missing from the end of the claim. Appropriate correction is required.

New Rejections Necessitated by Amendment

Claim Rejections - 35 USC § 112

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 52-62, 64, 65, 68, 72-75, and 78 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. One of skill in the art would not be able to determine the scope of the presently claimed invention. For example, independent claims 52 and 78 state that the substrate is comprised of K which includes C which is a biological modified

macromolecule bearing an unsaturated group. However, independent claims 52 and 78 also state that "wherein each cell may include an immobilized macromolecule". Therefore, it is not clear if the macromolecule of C is the same as the optional macromolecule or not. In addition, if the macromolecule is optional then how does K always comprise C?

Maintained Rejections

Claim Rejections - 35 USC § 102/35 USC § 103

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claim 78 is rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Vasiliskov et al., Fabrication of Microarray of Gel-Immobilized Compounds on a Chip by Copolymerization, Biotechniques, 27: 592-606, 1999 (provided by applicants in the IDS).

For present claim 78, Vasiliskov et al. teach microarrays of gel cells with immobilized modified DNA (C) wherein acrylamide (A), bisacrylamide (B), TEMED (D), water, glycerol,

etc. are copolymerized (please refer to the entire reference particularly the abstract; Materials and Methods; Figures 2-3).

Therefore, the presently claimed invention is anticipated by the teachings of Vasiliskov et al.

Arguments and Response

11. Applicants' arguments directed to the rejection under 35 USC 102 (b) as being anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Vasiliskov et al. for claim 78 were considered but are not persuasive for the following reasons.

Applicants' previous arguments of record are incorporated herein.

Applicants' arguments are not convincing since the teachings of Vasiliskov et al. anticipate or, in the alternative, render prima facie obvious the biochip of the instant claims.

Regarding the additional reagents (i.e. promoter of polymerization, a photo-initiator, or allyl oligonucleotides) taught by Vasiliskov et al., it is noted that the presently claimed invention has open (i.e. comprising) claim language and, therefore, does not exclude additional reagents. See MPEP § 2111.03.

Regarding the attorney arguments regarding unexpected results and advantages, attorney argument is not evidence. See MPEP § 2145.

In addition, it is noted that the unexpected result and advantages discussed refer to the process of making the biochip and not to the final product which is presently claimed. See MPEP § 2113 regarding product-by-process limitations.

12. Claim 78 is rejected under 35 U.S.C. 103(a) as obvious over Rehman et al., Immobilization of acrylamide-modified oligonucleotides by co-polymerization, *Nucleic Acids Research*, 27(2): 649-655, 1999 (provided by applicants in the IDS).

For present claim 78, Rehman et al. teach microarrays of gel cells with immobilized acrylamide-modified DNA (C) wherein acrylamide (A), bisacrylamide (B), APS and TEMED (D), water, and glycerol are copolymerized (please refer to the entire reference particularly the abstract; Materials and Methods; Figures 2-3; Figure 1).

Therefore, the presently claimed invention is anticipated by the teachings of Rehman et al.

Arguments and Response

13. Applicants' arguments directed to the rejection under 35 USC 102 (b) as being anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Rehman et al. for claim 78 were considered but are not persuasive for the following reasons.

Applicants' previous arguments of record are incorporated herein.

Applicants' arguments are not convincing since the teachings of Rehman et al. anticipate the biochip of the instant claims.

The presently claimed invention is drawn to a biochip and not the process of making the biochip. Therefore, only the structural limitations regarding the final product will be provided patentable weight (see MPEP § 2113).

It is not clear why the lack of disclosure of a photo- or a chemical initiator and APS (ammonium persulfate) and TEMED in the present application is pertinent to the teachings of Rehman et al. or the present claims. Although the claims are interpreted in light of the

specification, limitations from the specification (i.e. including negative limitations) are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Regarding the additional reagents (i.e. photo-initiator or acrylamide oligonucleotides) taught by Rehman et al., it is noted that the presently claimed invention has open (i.e. comprising) claim language and, therefore, does not exclude additional reagents. See MPEP § 2111.03.

Regarding the reference relied upon, a copy was not received. Therefore, the reference has not been considered.

Claim Rejections - 35 USC § 103

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

15. Claims 52-62, 64, 65, 68, 72-75, and 78 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vasiliskov et al., *Fabrication of Microarray of Gel-Immobilized Compounds on a Chip by Copolymerization*, *Biotechniques*, 27: 592-606, 1999 (provided by applicants in the IDS) and Solomon et al. U.S. Patent 6,585,873 filed March 22, 2000.

For present claims 52-62, 64-65, 68, 74-75, and 78, Vasiliskov et al. teach microarrays of gel cells with immobilized modified DNA (C) wherein acrylamide (A), bisacrylamide (B),

TEMED (D), water, and glycerol are copolymerized (please refer to the entire reference particularly the abstract; Materials and Methods; Figures 2-3).

However, Vasiliskov et al. does not teach the species of (B) recited in present claim 52.

For present claim 52, Solomon et al. teach hydrophilic gels comprising copolymerized acrylamide, N,N'-methylenebisacrylamide, DMF, glycerol, and water (please refer to the entire specification particularly the abstract; Figure 1; columns 1-2, 6-7, 9; Examples 1-20).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to modify the hydrogel taught by Vasiliskov et al. with specific species of bisacrylamide taught by Solomon et al.

One having ordinary skill in the art would have been motivated to do this because Solomon et al. teaches that N,N'-methylenebisacrylamide and acrylamide copolymerization is conventional in the art (please refer to column 1, lines 25-28).

One of ordinary skill in the art would have had a reasonable expectation of success in the modification of the hydrogel taught by Vasiliskov et al. with specific species of bisacrylamide taught by Solomon et al. because of the examples taught by Solomon et al. (see Example 5).

Therefore, the modification of the hydrogel taught by Vasiliskov et al. with specific species of bisacrylamide taught by Solomon et al. render the instant claims *prima facie* obvious.

Arguments and Response

16. Applicants' arguments directed to the rejection under 35 USC 103 (a) as being unpatentable over Vasiliskov et al. and Solomon et al. for claims 52-62, 64, 65, 68, 72-75, and 78 were considered but are not persuasive for the following reasons.

Applicants contend that Solomon et al. does not teach a biological modified macromolecule because the proteins and DNA are in the gel and not in the substrate.

Applicants' arguments are not convincing since the teachings of Vasiliskov et al. and Solomon et al. render the biochip of the instant claims *prima facie* obvious.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Specifically, Vasiliskov et al. teach gel-immobilized compounds on chips containing oligos, DNA, or proteins (see the entire reference particularly Materials and Methods section). Solomon et al. is utilized to teach the species of (B) recited in present claim 52.

17. Claims 52-62, 64, 65, 68, 72-75, and 78 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rehman et al., Immobilization of acrylamide-modified oligonucleotides by copolymerization, *Nucleic Acids Research*, 27(2): 649-655, 1999 (provided by applicants in the IDS) and Solomon et al. U.S. Patent 6,585,873 filed March 22, 2000.

For present claims 52-62, 64-65, 68, 74-75, and 78, Rehman et al. teach microarrays of gel cells with immobilized acrylamide-modified DNA (C) wherein acrylamide (A), bisacrylamide (B), APS and TEMED (D), water, and glycerol are copolymerized (please refer to the entire reference particularly the abstract; Materials and Methods; Figures 2-3).

However, Rehman et al. doe not teach the species of (B) recited in claim 52.

For present claim 52, et al. Solomon teach hydrogels comprising acrylamide, N,N'-methylenebisacrylamide, DMF, glycerol, and water (please refer to the entire specification particularly the abstract; Figure 1; columns 1-2, 6-7, 9; Examples 1-20).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to modify the hydrogel taught by Rehman et al. with specific species of bisacrylamide taught by Solomon et al.

One having ordinary skill in the art would have been motivated to do this because Solomon et al. teaches that N,N'-methylenebisacrylamide and acrylamide copolymerization is conventional in the art (please refer to column 1, lines 25-28).

One of ordinary skill in the art would have had a reasonable expectation of success in the modification of the hydrogel taught by Rehman et al. with specific species of bisacrylamide taught by Solomon et al. because of the examples taught by Solomon et al. (see Example 5).

Therefore, the modification of the hydrogel taught by Rehman et al. with specific species of bisacrylamide taught by Solomon et al. render the instant claims *prima facie* obvious.

Arguments and Response

18. Applicants' arguments directed to the rejection under 35 USC 103 (a) as being unpatentable over Rehman et al. and Solomon et al. for claims 52-62, 64, 65, 68, 72-75, and 78 were considered but are not persuasive for the following reasons.

Applicants contend that Solomon et al. does not teach a biological modified macromolecule because the proteins and DNA are in the gel and not in the substrate.

Applicants' arguments are not convincing since the teachings of Rehman et al. and Solomon et al. render the biochip of the instant claims *prima facie* obvious.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Specifically, Rehman et al. teach copolymerization of acrylamide modified oligos into polyacrylamide copolymer (see the entire reference particularly Materials and Methods section). Solomon et al. is utilized to teach the species of (B) recited in present claim 52.

Double Patenting

19. Claims 52-62, 64, 65, 68, 72-75, and 78 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-25 of U.S. Patent 7,846,656. Although the conflicting claims are not identical, they are not patentably distinct from each other because both the presently claimed invention and the invention as claimed in U.S. Patent 7,846,656 result in the same end product.

For present claims 52-62, 64, 65, 68, 72-75, and 78, U.S. Patent 7,846,656 claims methods of making biochips comprising immobilized molecules made by the method of polymerizing a composition comprising $K = aA + bB + cC + eE + fF$ wherein A is acrylamide, etc.; B is N,N'-methylenebisacrylamide, etc.; C is oligonucleotide, nucleic acid, etc.; D is a medium for performing polymerizing immobilization; and E is water, etc. and wherein and a, b, c, d, and e are percentages (X) of each ingredient in the composition wherein for solids X is $m/v \times 100\%$ and for liquids X is $v/v \times 100\%$ wherein the total content of monomer and cross-linking agent is in a range from 3 to 40% ($3 \leq (a+b) \leq 40\%$) and a monomer to cross-linking agent ration

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being within a range of 97:3 to 60:40 and percentages of C, D, and E ingredients being within a range of $0.0001\% \leq c \leq 10\%$; $0\% \leq d \leq 90\%$; $5\% \leq e \leq 95\%$ (please refer to claims 1-25).

and will not be held in abeyance (see MPEP § 714.02).

Conclusion

20. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Kalabina et al., 1996, Polymer Ultrathin Films with Immobilized Photosynthetic Reaction Center Proteins, *Biochimica et Biophysica Acta*, 1284: 138-142 and Zlatanova et al., 2001, Gel-Immobilized Microarrays of Nucleic Acids and Proteins, *Methods in Molecular Biology*, 170: 17-38.

Future Communications

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amber D. Steele whose telephone number is (571)272-5538. The examiner can normally be reached on Monday through Friday 9:00AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Amber D. Steele/
Primary Examiner, Art Unit 1639